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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,944	01/26/2006	Shunji Yunoki	TPP31793	8443

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EXAMINER
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KOSSON, ROSANNE

ART UNIT	PAPER NUMBER
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1652

MAIL DATE	DELIVERY MODE
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07/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/565,944	YUNOKI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Rosanne Kosson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 22 June 2007.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 5-16 and 19-23 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-4, 17 and 18 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 26 January 2006 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____.
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____.	6) <input type="checkbox"/> Other: _____.

**DETAILED ACTION**

***Election/Restrictions***

Applicants' election without traverse of Group I, claims 1-4 and 16-23 in the reply filed on June 22, 2007 is acknowledged. Applicants' election with traverse of the species of a cell carrier, amended to read "scaffold for cell culture," claims 17-18, is also acknowledged. Claims 5-16 and 19-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to non-elected inventions, there being no allowable generic or linking claim. Claims 17 and 18 have been amended. No claims have been canceled or added. Accordingly, claims 1-4, 17 and 18 are examined on the merits herewith.

In their traversal, Applicants assert that the restriction would entail additional expenses on their part, due to additional applications for the non-elected species, although they remind Examiner that upon the allowance of a generic claim, they are entitled to a reasonable number of additional species. Applicants also assert that additional future applications would require more references having to be reviewed in future searches for related subject matter.

In reply, as noted in the previous Office action and by Applicants, if a generic claim is found to be allowable, a reasonable number of additional claimed species will be searched and examined. As for additional applications and their expenses, these are not criteria in restriction, and filing multiple inventions in one application is elective on Applicants' part. As for future searches retrieving additional references to be reviewed, this is also not a criterion in restriction.

Accordingly, the restriction requirement is maintained and is made final.

***Drawings***

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawings filed with the application are not of sufficient quality and do not show any visible features of the claimed product. A white circle or ellipse with a black background are all that is visible in Figs. 1-3. The irregular, striated fibers in Fig. 4 may be collagen, but no cells are visible. Applicants are advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

The drawings are objected to under 37 CFR 1.83(a) because they fail to show a cell culture scaffold made of stretchable collagen as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the

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examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

## **INFORMATION ON HOW TO EFFECT DRAWING CHANGES**

### **Replacement Drawing Sheets**

Drawing changes must be made by presenting replacement sheets which incorporate the desired changes and which comply with 37 CFR 1.84. An explanation of the changes made must be presented either in the drawing amendments section, or remarks, section of the amendment paper. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). A replacement sheet must include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of the amended drawing(s) must not be labeled as "amended." If the changes to the drawing figure(s) are not accepted by the examiner, applicant will be notified of any required corrective action in the next Office action. No further drawing submission will be required, unless applicant is notified.

Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and within the top margin.

### **Annotated Drawing Sheets**

A marked-up copy of any amended drawing figure, including annotations indicating the changes made, may be submitted or required by the examiner. The annotated drawing sheet(s) must be clearly labeled as "Annotated Sheet" and must be presented in the amendment or remarks section that explains the change(s) to the drawings.

### **Timing of Corrections**

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in ABANDONMENT of the application.

If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 2, 17 and 18 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims recite a stretchable collagen material, or a stretchable fish collagen material, which reads on naturally occurring collagen or fish collagen. These are products of nature, and the invention as claimed does not reflect human intervention, i.e., purification from the natural source. As discussed in the previous Office action, Ohyabu et al. (US 4,275,084) disclose stretchable collagen, and they disclose that naturally occurring collagen in animal muscle is stretchable, maintaining the shape and texture of the muscle (see col. 1, lines 26-50). Claim 1 may be amended to recite a purified or an isolated stretchable collagen.

With respect to claim 17, the intended uses of a scaffold for cell culture and of providing elastic stimuli to incubated cells do not materially change the claimed product, and, as a result, they have no patentable weight. With respect to claim 18, naturally occurring collagen is a cell culture scaffold or carrier, because cells grow on it *in situ*. For example, in joints, chondrocytes (cartilage cells) grow on the collagen, and, in skin, epithelial cells grow on the collagen.

Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim recites that the cell culture scaffold is used to give elastic stimuli to

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incubated cells. This concept appears only once in the specification, item no. 17 on p. 10. It cannot be determined from the specification what an elastic stimulus is or how an elastic stimulus can be imparted to a cell by a collagen scaffold. Thus, the meaning of the claim is unclear, rendering it indefinite. Appropriate correction is required. For example, the words "giving elastic stimuli to" may be deleted.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Andre et al. (US 6,541,023), as evidenced by Ohyabu et al. (US 4,275,084). Andre et al. disclose that collagen, prepared as a matrix, gel or film is a particularly good substrate for cell development, including human cell development. A preferred collagen is cross-linked fish collagen, which is cross-linked to inhibit enzymatic degradation (see col. 1, lines 15-48). A cell culture scaffold comprising fish collagen cross-linked with a carbodiimide (a carbodiimide that is soluble in aqueous solution) is disclosed in Example 3, col. 7.

Regarding the claim limitation that the collagen is stretchable, as discussed previously and above, Ohyabu et al. disclose that being stretchable is a naturally occurring property of collagen. Therefore, this claim limitation does distinguish Applicants' invention from the prior art. Moreover, Andre et al. use the same type of collagen as Applicants, collagen from fish skin. The prior art collagen is as stretchable as Applicants' collagen.

Regarding claim 17, as discussed above, the intended use of giving elastic stimuli to

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incubated cells is a claim limitation that does not materially change the composition and that, therefore, has no patentable weight.

In view of the foregoing, a holding of anticipation is required.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rosanne Kosson *Rosanne Kosson*  
Examiner, Art Unit 1652

rk/2007-07-11

/Rebecca Prouty/  
Primary Examiner  
Art Unit 1652